

Substitute for form 1449A/PTO

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Sheet 1 of 5

Complete if Known

Application Number	10/790,562
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	1653 1636
Examiner Name	W. Schlapkohl
Attorney Docket Number	2578-4038.3US

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 2 of 5

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Application Number	10/790,562
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First Named Inventor	Hateboer et al.
Group Art Unit	1653 1636 <i>unf</i>
Examiner Name	W. Schlappkohl
Attorney Docket Number	2578-4038.3US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>unf</i>		ALKHATIB et al., "Expression of Bicistronic Measles Virus P/C mRNA by Using Hybrid Adenovirus: Levels of C Protein Synthesized In Vivo Are Unaffected by the Presence or Absence of the Upstream P Initiator Codon," Journal of Virology, November 1988, pp. 4059-4068, Vol. 62, No. 11.	
<i>unf</i>		ALKHATIB et al., "High-Level Eucaryotic In Vivo Expression of Biologically Active Measles Virus Hemagglutinin by Using an Adenovirus Type 5 Helper-Free Vector System," Journal of Virology, August 1988, pp. 2718-2727, Vol. 62, No. 8.	
<i>unf</i>		BERG et al., High-Level Expression of Secreted Proteins from Cells Adapted to Serum-Free Suspension Culture, Research Report, BioTechniques, 1993, pp. 972-78, Vol. 14, No. 6.	
<i>unf</i>		BROWN et al., "Evaluation of Cell Line 293 for Virus isolation in Routine Viral Diagnosis," Journal of Clinical Microbiology, April 1986, pp. 704-708, Vol. 23, No. 4.	
<i>unf</i>		BUKREYEV et al., "Recombinant Respiratory Syncytial Virus from Which the Entire SH Gene Has Been Deleted Grows Efficiently in Cell Culture and Exhibits Site-Specific Attenuation in the Respiratory Tract of the Mouse," Journal of Virology, December 1997, pp. 8973-8982, Vol. 71, No. 12.	
<i>unf</i>		CARAVOKYRI et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements that Deficiency of pIX Mutant Adenovirus Type 5," Journal of Virology, November 1995, pp. 6627-6633, Vol. 69, No. 11.	
<i>unf</i>		Certificate of deposit of the PER.C6 cell line (ECACC deposit under number 96022940).	
<i>unf</i>		CICCARONE et al., "Lipofectamine 2000 Reagent for Transfection of Eukaryotic Cells," Focus, 1999, pp. 54-55, Vol. 21, No. 2.	
<i>unf</i>		COTE et al., Serum-Free Production of Recombinant Proteins and Adenoviral Vectors by 293SF-3F6 Cells, Biotechnology and Bioengineering, September 5, 1998, pp. 567-75, Vol. 59, No. 5.	
<i>unf</i>		DuBRIDGE et al., "Analysis of Mutation in Human Cells by Using an Epstein-Barr Virus Shuttle System," Molecular and Cellular Biology, January 1987, pp. 397-387, Vol. 7, No. 1.	
<i>unf</i>		ENDO et al., Growth of Influenza A Virus in Primary, Differentiated Epithelial Cells Derived from Adenoids, Journal of Virology, Mar. 1996, pp. 2055-58, Vol. 70, No. 3.	
<i>unf</i>		FALLAUX et al., Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors, Human Gene Therapy, January 20, 1996, pp. 215-222, Vol. 7.	

Examiner Signature	<i>unf Schlappkohl</i>	Date Considered	3-15-2006
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		Group Art Unit	1683 1636 <i>Wdf</i>
		Examiner Name	W. Schlapkohl
Sheet 3 of 5	Attorney Docket Number	2578-4038.3US	

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<i>Wdf</i>		Figure 1 submitted by Opponent I.	
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<i>Wdf</i>		GARNIER et al., Scale-up of the adenovirus expression system for the production of recombinant protein in human 293S cells, Cytotechnology, 1994, pp. 145-55, Vol. 15.	
<i>Wdf</i>		GenBank Accession No. X02996.1, 1993, "Adenovirus type 5 left 32% of the genome."	
<i>Wdf</i>		GIBCO cell culture, A Guide to Serum-Free Cell Culture, www.invitrogen.com	
<i>Wdf</i>		GRAHAM et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," J. Gen. Virol., 1997, pp. 59-72, Vol. 36.	
<i>Wdf</i>		GRAHAM et al., "Growth of 293 cells in suspension culture," J Gen Virol, March 1987, pp. 937-940, Vol. 68.	
<i>Wdf</i>		GRAHAM, Cell Lines, Promochem (visited 04.10.2005) <http://www.lgcpromochem-atcc.com/SearchCatalogs/longview.cfm?view=ce,1146678...>.	
<i>Wdf</i>		HOLZER et al., "Construction of a Vaccinia Virus Deficient in the Essential DNA Repair Enzyme Uracil DNA Glycosylase by a Complementing Cell Line," Journal of Virology, July 1997, pp. 4997-5002, Vol. 71, No. 7.	
<i>Wdf</i>		INOUE et al., Production of Recombinant Human Monoclonal Antibody Using ras-Amplified BHK-21 Cells in a Protein-free Medium, Biosci. Biotech. Biochem., 1996, pp. 811-17, Vol. 60, No. 5.	
<i>Wdf</i>		Interlocutory Decision of the Opposition Division of 21 July 2003 in the case EP 0 695 351(European application 94 913 174.2)	

Examiner Signature	<i>Wdf/Schlapkohl</i>	Date Considered	3-15-2006
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Sheet 4

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First Named Inventor	Hateboer et al.
Group Art Unit	1653 1636 <i>WLF</i>
Examiner Name	W. Schlapkohl
Attorney Docket Number	2578-4038.2US

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>WLF</i>		LOPEZ et al., Efficient production of biologically active human recombinant proteins in human lymphoblastoid cells form integrative and episomal expression vectors, Gene, 1994, pp. 285-91, Vol. 148.	
<i>WLF</i>		LUTZ et al., "The Product of the Adenovirus Intermediate Gene IX Is a Transcriptional Activator," Journal of Virology, July 1997, pp. 5102-5109, Vol. 71, No. 7.	
<i>WLF</i>		MANSERVIGI et al., "Protection from Herpes Simplex Virus Type 1 Lethal and Latent Infections by Secreted Recombinant Glycoprotein B Constitutively Expressed in Human Cells with a BK Virus Episomal Vector," Journal of Virology, January 1990, pp. 431-436, Vol. 64, No.1.	
<i>WLF</i>		Marketing Authorization and Scientific Discussion for Xigris.	
<i>WLF</i>		MASSIE et al., Improved Adenovirus Vector Provides Herpes Simplex Virus Ribonucleotide Reductase R1 and R2 Subunits Very Efficiently, Biotechnology, June 1995, pp. 602-08, Vol. 13.	
<i>WLF</i>		MERTEN et al., Production of Influenza Virus in Cell Cultures for Vaccine Preparation, Exp Med Biol., 1996, pp. 141-51, Vol. 397.	
<i>WLF</i>		NEUMANN et al., "Generation of influenza A viruses entirely from cloned cDNAs," Proc. Natl. Acad. Sci., August 1999, pp. 9345-9350, Vol. 96.	
<i>WLF</i>		Notice of Opposition to a European Patent for I 161 548 by Sero.	
<i>WLF</i>		Opposition against European patent I 108 878 B1 filed October 5, 2005 in the name and on behalf of CEVEC Pharmaceuticals GmbH.	
<i>WLF</i>		Opposition against European patent I 161 548 B1 filed November 16, 2005, in the name and on behalf of CEVEC Pharmaceutical GmbH.	
<i>WLF</i>		Opposition against European patent I 108787 filed October 5, 2005 in the name and on behalf of Probiogen AG.	
<i>WLF</i>		ORY et al., "A stable human-derived packaging cell line for production of high titer retrovirus/vesicular stomatitis virus G pseudotypes," Proc. Natl. Acad. Sci., October 1996, pp. 11400-11406, Vol. 93.	

Examiner Signature	<i>WLF Schlapkohl</i>	Date Considered	3-15-2006
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		First Named Inventor	Hateboer et al.
		Group Art Unit	1653 1636 <i>inf</i>
		Examiner Name	W. Schlapkohl
Sheet 5 of 5	Attorney Docket Number	2578-4038.3US	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>inf</i>		PARKINSON et al., "Stable Expression of a Secretable Deletion Mutant of Recombinant Human Thrombomodulin in Mammalian Cells," The Journal of Biological Chemistry, 25 July 1990, pp. 12602-12610, Vol. 265, No. 21.	
<i>inf</i>		PAUL et al., Increased Viral Titer Through Concentration of Viral Harvests from Retroviral Packaging Lines, Human Gene Therapy, 1993, pp. 609-15, Vol. 4.	
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<i>inf</i>		PubMed listing of abstracts (visited 04.10.2005) < http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=pubmed .	
<i>inf</i>		REINA et al., Comparison of Madin-Darby Canine Kidney cells (MDCK) with a Green Monkey Continuous Cell Line (Vero) and Human Lung Embryonated Cells (MRC-5) in the Isolation of Influenza A Virus from Nasopharyngeal Aspirates by Shell Vial Culture, Journal of Clinical Microbiology, July 1997, pp. 1900-01, Vol. 35, No. 7.	
<i>inf</i>		RHIM et al., "Development of Human Cell Lines from Multiple Organs," Annals of the New York Academy of Sciences, 2000, pp. 16-25, Vol. 919.	
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<i>inf</i>		STEVENS et al., "The N-Terminal Extension of the Influenza B Virus Nucleoprotein Is Not Required for Nuclear Accumulation or the Expression and Replication of a Model RNA," Journal of Virology, June 1998, pp. 5307-5312, Vol. 72, No. 6.	
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<i>inf</i>		YEAGER et al., Constructing immortalized human cell lines, Current Opinion Biotechnology, 1999, pp. 465-69, Vol. 10.	
<i>inf</i>		YEH et al., Adenoviral Vectors, pp. 25-42 of "Concepts in Gene Therapy," Publisher: Walter de Gruyter, New York.	
Examiner Signature	<i>W. Schlapkohl</i>		Date Considered
		3-15-2006	

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Group Art Unit	To be assigned 1636 waf
Examiner Name	To be assigned SCHLAPROHL waf
Attorney Docket Number	2578-4038.3US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
waf		US- 4,703,008	10-27-1987	Lin	
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Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
waf		#WO 95/05465	02-23-1995	Amgen Inc.		
		#WO 98/18926	05-07-1998	G.D. Searle & Co.		
		#WO 98/39411	09-11-1998	Baxter International Inc.		
		#WO 98/44141	10-08-1998	The University of British Columbia		
		#WO 99/05268	02-04-1999	Boehringer Mannheim GMBH		
		#WO 00/61164	10-19-2000	Kenneth S. Warren Laboratories		
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		#WO 01/38362 A2	03-12-2001	Crucell Holland B.V.		
		#WO 02/053580	07-11-2002	The Kenneth S. Warren Institute, Inc.		
		#WO 03/038100 A1	05-08-2003	Crucell Holland B.V.		
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		#WO 2004/003176	01-08-2004	The Kenneth S. Warren Institute, Inc.		
		#WO 2004/099396	11-18-2004	Crucell Holland B.V.		
		#EP 0 411 678	02-06-1991	Genetics Institute, Inc.		

Examiner
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waf schlaphohl

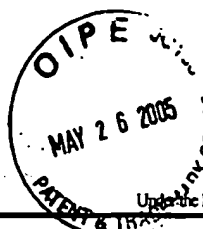
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Attorney Docket Number	2578-4038 3LIS

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way		#GHOSH-CHOUDHURY et al., Protein IX, a minor component of the human adenovirus capsid, is essential for the packaging of the full length genomes, The EMBO Journal, 1987, 6, 6009-6016.	
		#LOUIS et al., Cloning and Sequencing of the Cellular-Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line, Virology, 1997, pp. 423-29, Vol. 233.	NO COPY
		#NCBI Entrez Nucleotide accession number U38242.	DUPLICATE
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way		#PAU et al., Abstract, The human cell line PER.C6 provides a new manufacturing system for the production of influenza vaccines, Vaccine, Mar. 21, 2001, pp. 2116-21, Vol. 19, No. 17-19.	NO COPY

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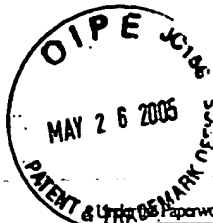
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 3

Complete if Known

Application Number	10/790,562
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	To be assigned 1636 waf
Examiner Name	To be assigned SCHLAPKOHL waf
Attorney Docket Number	2578-4038 31JS

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
mbf		#CARROLL et al., Abstract, Differential Infection of Receptor-modified Host Cells by Receptor-Specific Influenza Viruses, Virus Research, Sep. 1985, pp. 165-79, Vol. 3, No. 2.	
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		#PACITTI et al., Inhibition of Reovirus Type 3 Binding to Host Cells by Sialylated Glycoproteins Is Mediated through the Viral Attachment Protein, Journal of Virology, May 1997, pp. 1407-15, Vol. 61, No. 5, American Society for Microbiology.	
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		#HOLLISTER et al., Stable expression of mammalian beta1,4-galactosyltransferase extends the N-glycosylation pathway in insect cells, Glycobiology, 1998, pp. 473-80, Vol. 8, No. 5, IRL Press, United Kingdom.	
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		#WEIKERT et al., Engineering Chinese hamster ovary cells to maximize sialic acid content of recombinant glycoproteins, Nature Biotechnology, November 1999, pp. 1116-21, Vol. 17, No. 11, Nature Pub. Co., New York, NY, US.	
mbf		#MINCH et al., Tissue Plasminogen Activator Coexpressed in Chinese Hamster Ovary Cells with alpha(2,6)-Sialyltransferase Contains NeuAc-alpha(2,6)Gal-beta(1,4)Glc-N-AcR Linkages, Biotechnol. Prog., 1995, pp. 348-51, Vol. 11, No. 3.	
Examiner Signature	mbf schlapkoehl		Date Considered
			3-15-2006

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/549,463

Filed: September 3, 2002

For: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

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Complete if Known

Application Number	To be assigned
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Filing Date	March 1, 2004
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First Named Inventor	Hateboer et al.
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Group Art Unit	To be assigned	1636	WAT
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Examiner Name	To be assigned <u>SCHLAPKOHLE</u>
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Attorney Docket Number	2578-4038.3US
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Sheet	1	of	2
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
<i>WLF</i>		*WO 93/03163	02-18-1993	Fond Nat Transfusion		
<i>WLF</i>		*WO 97/00328	01-03-1997	Univ Leiden		
<i>WLF</i>		*WO 95/29994	11-09-1995	Univ Michigan		
<i>WLF</i>		*EP 0 185 573	06-25-1986	Pasteur Institut		

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3-15-2006

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Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	To be assigned
		Filing Date	March 1, 2004
		First Named Inventor	Hateboer et al.
		Group Art Unit	To be assigned <i>1636 waf</i>
		Examiner Name	To be assigned <i>SCHLAPKOHL waf</i>
		Attorney Docket Number	2578-4038.3US
Sheet	2	of	2

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
<i>waf</i>		*PCT International Search Report, PCT/NL00/00247, dated October 9, 2000, 3 pages.	
<i>waf</i>		*GHOSH-CHOUDHURY et al., Protein IX, a minor component of the human adenovirus capsid, is essential for the packaging of the full length genomes, The EMBO Journal, 1987, pp. 1733-39, Vol. 6, No. 6.	
<i>waf</i>		*LOUIS et al., Cloning and Sequencing of the Cellular-Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line, Virology, 1997, pp. 423-29, Vol. 233.	
<i>waf</i>		*NCBI Entrez Nucleotide accession number U38242.	
<i>waf</i>		*NCBI Entrez Nucleotide accession number NC_002018.	
<i>waf</i>		*NCBI Entrez Nucleotide accession number X02996 J01967 J01968 J01970 J01971 J01972 J01974 J01976 J01977 J01978 J01979 K00515 V00025 V00026 V00027 V00029.	
<i>waf</i>		*SETOGUCHI et al., "Stimulation of Erythropoiesis by in vivo gene therapy: Physiologic consequences of transfer of the human erythropoietin gene to experimental animals using an adenovirus vector," Blood, November 1, 1994, pp. 2946-53, Vol. 84, No. 9.	

Examiner Signature	<i>waf schlappkoehl</i>	Date Considered	3-15-2006
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